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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|-------------------|
| 10/601,355 | 06/23/2003 | Anthony David Auffret | PC22039A | 7465 |
| 28940 | 7590 | 12/17/2004 | | |
| AGOURON PHARMACEUTICALS, INC. 10350 NORTH TORREY PINES ROAD LA JOLLA, CA 92037 | | | EXAMINER | HAMLIN, DERRICK G |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1751 | |

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/601,355 | AUFFRET ET AL.  |
| | Examiner Derrick G. Hamlin | Art Unit 1751 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 June 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/2/03
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a process for preparing a stable hydrate, classified in class 252, subclass 70.
- II. Claim 20, drawn to a disodium salt of fosfluconazole, classified in class 424, subclass 401.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different hydrates.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Elsa Djuardi on 12/2/04 a provisional election was made without traverse to prosecute the invention of group 2, claim 20. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-19 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Evaluations of level of ordinary skill in the art requires consideration of factors such as various prior art approaches employed, types of problems encountered in the art, rapidity with which innovations are made, sophistication of technology involved, educational background of those actively working in the field, commercial success, failure of others, and the inventor's educational level.

The "person having ordinary skill" in this art has the capability of understanding the scientific and engineering principles applicable to the claimed invention. The references of record in this case reasonably reflect this level of skill.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/28169.

The reference teaches disodium salt of fosfluconazole. (page 10, example 2)

The reference does not teach the instant invention with sufficient specificity to constitute an anticipation. The reference fails to teach the specific hydrate.

The reference does teach the disodium salt of fosfluconazole, therefore there would be a reasonable expectation of success to modify the prior art to arrive at the instantly claimed invention because the prior art teaches disodium salt of fosfluconazole, which one of ordinary skill in the art would reasonably expect to form the instantly claimed hydrates when put in water. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create the instantly claimed hydrate from a disodium salt of fosfluconazole.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Derrick G. Hamlin whose telephone number is (571) 272-1317. The examiner can normally be reached on Monday-Fridays from ~8:30 AM to 5:00 PM.

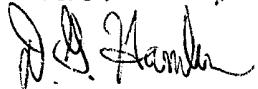
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Yogendra Gupta, can be reached on (571) 272-1316. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1751

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Derrick G. Hamlin

12/5/04



Necholus Ogden
PRIMARY EXAMINER